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Section 6.0 510(k) Summary

Submitter: InnerSpace
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Proprietary Name ACT I ICP Monitoring System
Common/Usual Name ICP Monitoring Device
Classification Name: ICP Monitoring Device

The legally marketed devices to which equivalence is claimed is the Model 110-4HM Monitoring System from Camino Laboratories

Description of Device: The catheter assembly consists of a single lumen catheter with a flaccid bladder at the distal end. The proximal end of the catheter terminates as a piston with an o-ring that forms one half of an air pump. The catheter is fixed in a titanium bolt screwed into the skull. A standard medical transducer is contained in the housing of a ISM-3000 series cable or pigtail. The housing includes a cylinder that forms the second half of an air pump. The act of seating the transducer housing on the catheter's piston injects a defined volume of air into the bladder and activates the system. The pressure in the bladder mirrors ICP. The cable attaches directly to a patient monitor, is reusable and can be sterilized by ETO.

Intended Use: To measure intracranial pressure in adults and pediatrics subject to elevated ICP.

The **ACT I ICP Monitoring System**, in combination with the **ISM –3000** series cable, is equivalent to the predicate device because:

It has the same intended use, namely to sense intracranial pressure.

The system performance complies with AMMI standards for intracranial pressure monitoring, modified to reflect the characteristics of the technology used.

It uses materials that have been shown to be biocompatible and function well in the intended application

The safety and effectiveness are similar or better than the existing device as demonstrated in laboratory and animal testing.

Safety
Laboratory testing has shown that the **ACT I** ICP monitoring System and the **ISM –3000** series cable or pigtail are safe in the following areas:

- Mechanical integrity Laboratory testing and basic design assure that no parts will come loose and be left in the patient.
- Operating life The IFU requires that the air in the bladder be replaced every shift by removing and replacing the transducer on the piston. Laboratory testing has established that the bladder can provide accurate readings for a period in excess of the once-per-shift recharging cycle called for in the IFU.

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- Set up There is no need to precondition or calibrate the system beyond the normal zeroing of the transducer. The transducer connects directly to the patient monitor.
- Biocompatibility Test results of a study performed by an independent third party demonstrate that the materials used in the device are safe for this application.
- Patient trauma The diameter of the stent within the bladder is .5 mm. The tube on which the bladder is mounted is 1.5 mm in diameter and extends just through the dura. The diameter of the filled bladder is ~4 Fr. The bladder is inserted into the parenchyma approximately 1.3 cm. The physical size of the in-situ portion is similar to the predicate device.
  Failure mode Bladder failure can be discerned by an abrupt rise in pressure when the transducer is removed and replaced. A failed transducer can be replaced at any time.

Effectiveness

Assessment in animals and laboratory testing has shown that the ISM **ACT I** bolt and catheter in combination with the **ISM 3000** series cable or pigtail are as or more effective than the predicate device in:

- Ease of use The catheter is mounted in a bolt as is the predicate device.
- Simplicity There is no need for an instrument between the sensor and monitor.
- Calibration The device need not be calibrated. The transducer is zeroed as usual.
- Sensor function The transducer can be checked at anytime by removing the transducer and checking the zero value on the patient monitor. This is not possible in other in-situ systems.

Donald E. Bobo Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Donald E. Bobo
President
Innerspace, Inc.
2933 South Pullman Street
Suite A
Santa Ana, California 92705

Re: K003905
Trade/Device Name: ACT I - ICP Monitoring System
Regulation Number: 882.1620
Regulatory Class: II
Product Code: GWM
Dated: March 14, 2001
Received: March 21, 2001

Dear Mr. Bobo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment

Indications for Use Statement

510(k) Number **K003905**

Device Name ACT I ICP Monitoring system

Indications For Use The use of the ACT I ICP Monitoring system by a qualified neurosurgeon is indicated when direct measurement of the intracranial pressure in the parenchyma is clinically important

Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003905

Prescription Use ✓ Or Over-The Counter Use ____
(Per 21 CFR 801.109)